#### **HEALTH AND SENIOR SERVICES**

#### DIVISION OF HEALTH CARE QUALITY AND OVERSIGHT

### **Hospice Licensing Standards**

Proposed Readoption N.J.A.C. 8:42C

Authorized By: Clifton R. Lacy, M.D., Commissioner,

Department of Health and Senior Services

(with the approval of the Health Care

Administration Board).

Authority: N.J.S.A. 26:2H-79, 80 and 81, and 26:2H-12.

Calendar Reference: See Summary below for explanation of

exception to the rulemaking calendar

requirement.

Proposal Number: PRN 2004-212

Submit comments by August 6, 2004 to:

John A. Calabria, Director

Certificate of Need and Acute Care Licensure

Program

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The agency proposal follows:

#### Summary

On April 4, 1997, P.L. 1997, c. 78 (as codified, N.J.S.A. 26:2H-79 through 81) was enacted. These statutes establish standards for hospice care programs operating in New Jersey, specifying the care and services that must be provided to hospice patients and their families (N.J.S.A. 26:2H-79). In addition, these statutes specify that hospice care programs must be certified to participate in the Medicare program, and licensed by the Department of Health and Senior Services (the Department) in order to operate in this State (N.J.S.A. 26:2H-80). Notably, N.J.S.A. 26:2H-80(e) exempts hospice care programs from compliance with certificate of need requirements set forth at N.J.S.A. 26:2H-7 through 10. N.J.S.A. 26:2H-81 authorizes the Department to develop rules for licensure, including relevant fees for initial and subsequent issuance of a license (which fee statutorily is limited to no more than \$2,000 for each license issued).

The rules proposed for readoption are intended to implement the provisions of N.J.S.A. 26:2H-79 through 81. Pursuant to N.J.S.A. 52:14B-5.1c, N.J.A.C. 8:42C expires on December 18, 2004. The Department expects that these readopted rules will continue to bring uniformity and consistency to the delivery of hospice care Statewide. The readoption of

these licensing rules will permit the Department to continue to ensure the quality of services provided by hospice care programs through effective inspections and appropriate enforcement. These rules were initially established through a collaborative effort between the Department and the Hospice Licensing Standard Advisory Committee. The Committee included representatives of the New Jersey Hospice and Palliative Care Organization, as well as hospice care providers.

Specifically, these rules establish requirements for the licensing of a hospice care program in New Jersey, as well as continued renewal of such a license. These rules are based on the standards for hospice participant certification established by Medicare. However, additional standards apply for hospice licensure, so that the hospice licensing standards are consistent with licensure requirements established for most health care facilities or services in New Jersey. For instance, these rules establish standards that are in addition to or exceed Medicare standards for employee health (especially those who have direct patient contact), patient rights, and infection control programs. In addition, these licensing rules specify the fees that must be paid to obtain an initial license and license renewal, as well as inspection fees.

To summarize, N.J.A.C. 8:42C-1 sets forth the purpose and scope of the rules, and the definitions used throughout the chapter.

N.J.A.C. 8:42C-2 establishes the process for making application for and obtaining a license and license renewal. Among other things, this subchapter establishes a suitability review procedure for those entities seeking guidance from the Department as to whether they are likely to meet the licensing requirements, and a determination of those areas in which they are weak.

N.J.A.C. 8:42C-3 sets forth the general requirements with which a hospice must comply in order to be licensed. Subchapter 3 includes health requirements for employees, specifies that hospices must have policy and procedure manuals for the organization and operation of the hospice that must be reviewed annually and updated as necessary, specifies those events which are reportable to the Department, and those reports that must be made to the State Board of Medical Examiners and other professional licensing boards.

N.J.A.C. 8:42C-4 sets forth standards for the administration of the hospice, including the qualifications and responsibilities of the administrator.

N.J.A.C. 8:42C-5 sets forth minimum patient rights.

N.J.A.C. 8:42C-6 provides standards for patient care services, including the role of the interdisciplinary team.

N.J.A.C. 8:42C-7 establishes standards for nursing services and homemaker-home health aide services.

N.J.A.C. 8:42C-8 sets forth standards for pharmacy and pharmaceutical supplies.

N.J.A.C. 8:42C-9 specifies the manner in which a hospice is to maintain medical records, including in the event that the hospice ceases operation.

N.J.A.C. 8:42C-10 requires that all hospices have an infection prevention and control program, and sets forth the minimum standards for such a program.

Because a 60-day comment period has been provided on this notice of proposal, this notice is excepted from the rulemaking calendar requirement pursuant to N.J.A.C. 1:30-3.3(a)5.

## **Social Impact**

N.J.S.A. 26:2H-79 through 81 mandates the Department to develop "standards and procedures" relating to the licensing of hospice care programs to ensure high-quality hospice services to the residents of New Jersey in a coordinated and cost-effective manner. The rules proposed for readoption maintain appropriate minimum requirements for the provision of hospice services in New Jersey and promote the delivery of these services at a high quality level.

The proposed readoption of these rules will benefit hospice patients, their families and caregivers, as well as hospice care programs. The

Department recognizes the positive social impact of the hospice care movement upon patient quality of life in this State. For chronically ill patients who meet the criteria for hospice care, this care is used as an alternative to institutionalization as well as a means of maintaining as much of an independent living status as possible for terminally ill individuals in the community. Hospice care has had a significant positive impact upon the quality of life for terminally ill individuals and their families because this type of care allows an individual to receive the diverse services needed during the final stage of his or her life, while residing at home with his or her family or in another place that has become home to the individual.

The proposed readoption of licensing rules for hospice care programs, together with the Medicare certification standards, serves to promote high-quality palliative care for terminally ill patients. The readoption of these rules will ensure the employment of qualified staff and a well trained group of volunteers, adequate record-keeping, and policies and procedures to govern patient care services, assuring that the needs of the patients and their families are met. Patients who remain in their homes (their own or another facility which has become their home) to receive palliative care retain their dignity and independence during the final stage of their life. The hospice care program minimizes further disruption to the patient's life, as well as that of his or her family, and provides him or her with a degree of control over the circumstances.

The proposed readoption of licensing rules for hospice care programs will play an important role in maintaining satisfactory levels of patient care for existing Medicare certified providers and monitoring the quality of care provided by new programs. The Department's proposed readoption of hospice licensure rules is essential for ensuring high quality care that is accessible and acceptable to the terminally ill consumer.

## **Economic Impact**

The Department foresees minimal financial consequences of the proposed readoption of licensure rules for hospice care programs, because the state licensing rules proposed for readoption build upon Medicare Certification Standards that the hospice care programs must already satisfy. It is anticipated that only minimal cost will be incurred by the industry and that cost will be readily absorbed. The Department will charge a nonrefundable fee for a license and any renewal thereof, as permitted by N.J.S.A. 26:2H-80b. In addition, hospices will incur a biennial inspection fee of \$1,000, as authorized by N.J.S.A. 26:2H-12.

No significant additional cost to the State is expected to result from the licensing and inspections of these facilities. The Department will have sufficient resources to conduct surveys, respond to complaints and develop and maintain appropriate licensure rules and has the authority to increase inspection fees if necessary within certain limits in accordance with N.J.S.A.

26:2H-12. The delivery of services by licensed hospice care programs is expected to result in considerable economic savings as opposed to the delivery of hospice care by larger institutions. Additionally, many health care authorities maintain that hospice care reduces the drain on personal finances for terminally ill patients and their families when compared with the other more costly alternatives, such as an inpatient setting.

## Federal Standards Analysis

The licensure rules being proposed for readoption are similar to the Medicare Certification Standards, established pursuant to 42 U.S.C. §1395, with which hospice care providers must comply in order to be Medicare certified. However, these rules proposed for readoption exceed the Federal Medicare certification standards in the following areas: employee health requirements, especially for direct patient care; policies and procedures regarding patient rights; and the establishment of an infection prevention and control program. The standards which exceed Medicare standards are consistent with companion licensure regulations for similar institutions in New Jersey. Retaining each of these areas in the readopted rules will serve to promote and protect the public health and welfare of terminally ill patients and their families/caregivers during the final stage of the patient's life. The Department believes it appropriate to exceed the federal standards because the health and welfare of hospice patients and their families is no less

important than the health and welfare of other patients under the care of state-licensed health care facilities or services. The costs of compliance are not significant, in that they require health screening tests, such as TB tests, and implementation of patient rights requirements within the context of provision of services generally. The infection prevention and control program required is appropriate in New Jersey, since a large number of hospice patients have communicable diseases. The cost of prevention is minimal, and is far less than the cost of treatment.

## Jobs Impact

The Department does not expect that any jobs will be generated or lost as a result of the rules proposed for readoption.

## Agriculture Industry Impact

The rules proposed for readoption will have no impact on the agriculture industry of the State of New Jersey.

# Regulatory Flexibility Analysis

The majority of New Jersey's hospice care programs may be considered small businesses, as that term is defined in the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et. seq. The proposed readoption of N.J.A.C. 8:42C will retain the same reporting, recordkeeping or compliance

requirements on such small businesses, although most of the requirements are already imposed by Federal Medicare requirements. Specifically, N.J.A.C. 8:42C-3, Personnel, establishes employee health requirements, especially for direct patient care. Costs, for tests and inoculations, if needed, are minimal. Also, N.J.A.C. 8:42C-5, Patient Rights, establishes policies and procedures regarding the rights of the patient. These procedures involve very little cost, and are primarily procedural. In addition, under N.J.A.C. 8:42C-10, Infection Prevention and Control, an infection prevention and control program is required. This program involves very little additional cost, and is primarily a procedural requirement, with no change in capital costs.

Professional services may be employed by facilities, but are not required by these rules.

The Department is not proposing through this readoption to lower or offer different standards for compliance by hospice care programs that may be small businesses. The Department believes that the need to assure the health and welfare of a hospice patient and his or her family is the same regardless of whether the patient is receiving care from a large or smaller hospice care program. The Department notes that a hospice care program may seek waiver of certain of the licensing requirements, but in doing so, the application must provide an alternative proposal to ensure patient safety that meets the satisfaction of the Department.

# **Smart Growth Impact**

The rules proposed for readoption shall not have an impact on the achievement of smart growth and the implementation of the State Development and Redevelopment Plan.

<u>Full text</u> of the proposed readoption may be found in the New Jersey

Administrative Code at N.J.A.C. 8:42C.